Remarks

Applicants have amended the title of the invention as requested by the Examiner. Applicants have also canceled withdrawn claims 11, 13, 17-20, and 22. No new matter has been added.

Claims 23-42 are pending.

I. Objections to the Specification

The Examiner has objected to the title of the invention as allegedly non-descriptive of the claimed invention. *See* Paper No. 7. page 4.

In response, Applicants have amended the title to "Nucleic Acids Encoding Human Serpin Polypeptide HMCIS41." Accordingly, Applicants believe that the instant objection has been obviated and should be reconsidered and withdrawn.

II. Rejection of the Claims under 35 U.S.C. §§ 101 and 112, First Paragraph

The Examiner has rejected claims 23-42 under 35 U.S.C. § 101 because the invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility. (*See* Paper No. 7, pages 4-8.) In particular, the Examiner contends that:

> the claimed invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant nucleic acid and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

The Examiner has further rejected claims 23-42 under 35 U.S.C. § 112, first paragraph, because one skilled in the art would allegedly not know how to use the claimed invention, based on the supposed lack of either a specific and substantial asserted utility or a well established utility.

Applicants respectfully disagree and traverse these rejections.

A rejection under 35 U.S.C. § 101 is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. *See* M.P.E.P. §§ 2107.01(II) – (III) (7th Ed. Rev. 1, Feb. 2000). In addition, an applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."); *see also* M.P.E.P. § 2107.01 at 2100-29; Utility Examination Guidelines, 66

Fed. Reg. 1092, 1098 (January 5, 2001). Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. *See* M.P.E.P. § 2107.01(II)(B); Utility Examination Guidelines at 1098.

Moreover, the Examiner must establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. *See* M.P.E.P. § 2107.01(II)(A); Utility Examination Guidelines at 1098-99. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *See id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants' assertion of utility. *See id.*; *see also In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, Applicants respectfully assert that the Examiner has not met the required burden.

Applicants point out that the Utility Examination Guidelines require an evaluation of the utilities taught in the closest prior art. *See* Utility Examination Guidelines at 1098. In the instant case, while the Examiner addresses the homology of the claimed polynucleotides to human placental thrombin inhibitor (SerpinB6), the Examiner contends that the claimed nucleic acid and encoded polypeptide "share only 35% homology" to that protein and the polynucleotide that encodes it. Applicants respectfully disagree, and assert that the polypeptide of SEQ ID NO:7 is at least 60% identical to SerpinB6 in the overlapping regions, and as much as 90% similar in those regions. *See* alignment attached as Exhibit A. Moreover, SEQ ID NO:7 shares similar homology to other serpin family members, such as SerpinB8 and SerpinB9. *See* alignments attached as Exhibit B. Thus, contrary to the Examiner's assertion, this substantial homology would allow one skilled in the art to reasonably conclude that the claimed invention was also a member of the type B serine protease inhibitor family. Moreover, Applicants have disclosed that the claimed polynucleotides are expressed in cancer, such as adrenal gland tumors, and thus could be used for cancer diagnosis. Applicants point out that expression levels of the related family member SerpinB9 have been shown to predict clinical outcome in lymphoma (*see* ten Berge et al, attached as Reference C), making it more likely than not that one skilled in the art would conclude that the claimed polynucleotides could be used for cancer diagnosis.

In view of the above, Applicants respectfully submit that the presently claimed invention possesses specific, substantial, credible, and well-established utilities which constitute patentable utilities under 35 U.S.C. § 101. Because Applicants' assertions of utility are sufficient to satisfy

the requirements of 35 U.S.C. § 101, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 101 be reconsidered and withdrawn.

Further, the Federal Circuit and its predecessor determined that the utility requirement of 35 U.S.C. § 101 and the how to use requirement of 35 U.S.C. § 112, first paragraph, have the same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV); Utility Examination Guidelines at 1098. As discussed above, the specification teaches specific and well-established utilities of the claimed invention, thereby enabling the skilled artisan to use the claimed polynucleotides. Since the specification teaches how to use the claimed polynucleotides with only routine experimentation and the specification describes specific and immediate utilities for the claimed invention, Applicants submit that the full scope of the claims is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered.

III. Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph

The Examiner has also rejected claims 33-42 under 35 U.S.C. § 112, first paragraph, asserting that there is no indication in the specification as to public availability of the deposit. Paper No. 7, pages 8-9. In particular, the Examiner has required that Applicants provide assurances regarding viability and access to material deposited under terms of the Budapest Treaty.

In response, Applicants' representative hereby gives the following assurance by signature below:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on March 15, 1999, accepted by the ATCC, tested and declared viable, and given ATCC Accession Number 203843. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 203843 will be irrevocably removed upon the grant of a patent based on the

instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number 203843 is enclosed herewith.

With respect to the further statements requested by the Examiner, Applicants respectfully assert that for deposits made under the Budapest Treaty, there is no requirement for such further statements in 37 C.F.R. §§ 1.801-1.809. *See, e.g.,* M.P.E.P. § 2408 ("Unless applicant indicates that the deposit has been made under the Budapest Treaty, applicant must indicate the term for which the deposit has been made."); § 2409 ("Under the Budapest Treaty, there is a requirement that the deposit be tested for viability before it is accepted. Thus, a mere statement by an applicant, an authorized representative of applicant or the assignee that the deposit has been accepted under the Budapest Treaty would satisfy 37 CFR 1.807."); and § 2410.01 ("Consequently, the mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would satisfy all conditions of these regulations except the requirement that all restrictions on access be removed on grant of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).") (emphasis added). Accordingly, Applicants submit that the above statement is sufficient to fully comply with the requirements of 37 C.F.R. §§ 1.801-1.809. Should the Examiner disagree, Applicants respectfully request that the Examiner more particularly point out the basis for requiring additional statements in light of M.P.E.P. §§ 2408-2410.01.

In light of the above, Applicants submit that the instant rejection under 35 U.S.C. § 112, first paragraph has been obviated, and should be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time

under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: November 3, 2003

Respectfully submitted,

By _____

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>gi|28077085 ref|NP_004559.3| (NM_004568) serine (or cysteine) proteinase
           inhibitor, clade B (ovalbumin), member 6; protease inhibitor 6
           (placental thrombin inhibitor) [Homo sapiens]
           Length = 376

  Plus Strand HSPs:

 Score = 126 (49.4 bits), Expect = 2.5e-48, Sum P(2) = 2.5e-48
 Identities = 24/31 (77%), Positives = 28/31 (90%), Frame = +1

Query:    52 MDALSEANGTFALNLLKKLGENNSNNLFFSP 144
             MD L+EANGTFALNLLK LG++NS N+FFSP
Sbjct:     1 MDVLAEANGTFALNLLKTLGKDNSKNVFFSP 31

 Score = 404 (147.3 bits), Expect = 2.5e-48, Sum P(2) = 2.5e-48
 Identities = 81/134 (60%), Positives = 103/134 (76%), Frame = +3

Query:   102 KARGKQLKQLIFF-PMSISSALAMVFMGAKGNTAAQMSQALCFSKIGGEDGDIHRGFQSL 278
             K  GK   + +FF PMS+S ALAMV+MGAKGNTAAQM+Q L F+K GG  GDIH+GFQSL
Sbjct:    17 KTLGKDNSKNVFFSPMSMSCALAMVYMGAKGNTAAQMAQILSFNKSGG-GGDIHQGFQSL 75

Query:   279 LVAINRTDTEYVLRTANGLFGEKSYDFLTGFTDSCGKFYQATIKQLDFVNDTEKSTTRVN 458
             L  +N+T T+Y+LR AN LFGEKS DFL+ F DSC KFYQA +++LDF++  EKS   +N
Sbjct:    76 LTEVNKTGTQYLLRVANRLFGEKSCDFLSSFRDSCQKFYQAEMEELDFISAVEKSRKHIN 135

Query:   459 SWVADKTKAWKIIQ 500
             +WVA+KT+  KI +
Sbjct:   136 TWVAEKTEG-KIAE 148
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>gi|4505791 ref|NP_002631.1| (NM_002640) serine (or cysteine) proteinase
           inhibitor, clade B (ovalbumin), member 8; protease inhibitor 8
           (ovalbumin type) [Homo sapiens]
           Length = 374

  Plus Strand HSPs:

 Score = 104 (41.7 bits), Expect = 1.9e-44, Sum P(2) = 1.9e-44
 Identities = 22/32 (68%), Positives = 26/32 (81%), Frame = +1

Query:    52 MDALSEANGTFALNLLKKLGE-NNSNNLFFSP 144
             MD L EANGTFA++L K LGE +NS N+FFSP
Sbjct:     1 MDDLCEANGTFAISLFKILGEEDNSRNVFFSP 32

 Score = 389 (142.0 bits), Expect = 1.9e-44, Sum P(2) = 1.9e-44
 Identities = 77/120 (64%), Positives = 92/120 (76%), Frame = +3

Query:   123 KQLIFFPMSISSALAMVFMGAKGNTAAQMSQALCFSKIGGEDGDIHRGFQSLLVAINRTD 302
             + + F PMSISSALAMVFMGAKG+TAAQMSQALC  K    DGDIHRGFQSLL  +NRT
Sbjct:    26 RNVFFSPMSISSALAMVFMGAKGSTAAQMSQALCLYK----DGDIHRGFQSLLSEVNRTG 81

Query:   303 TEYVLRTANGLFGEKSYDFLTGFTDSCGKFYQATIKQLDFVNDTEKSTTRVNSWVADKTK 482
             T+Y+LRTAN LFGEK+ DFL  F + C KFYQA +++L F  DTE+    +N WVA+KT+
Sbjct:    82 TQYLLRTANRLFGEKTCDFLPDFKEYCQKFYQAELEELSFAEDTEECRKHINDWVAEKTE 141
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>gi|4758906 ref|NP_004146.1| (NM_004155) serine (or cysteine) proteinase
           inhibitor, clade B (ovalbumin), member 9; protease inhibitor 9
           (ovalbumin type) [Homo sapiens]
           Length = 376

  Plus Strand HSPs:

 Score = 81 (33.6 bits), Expect = 1.4e-34, Sum P(2) = 1.4e-34
 Identities = 18/32 (56%), Positives = 25/32 (78%), Frame = +1

Query:    52 MDALSEANGTFALNLLKKLGENN-SNNLFFSP 144
             M+ LS A+GTFA+ LLK L ++N S+N+F SP
Sbjct:     1 METLSNASGTFAIRLLKILCQDNPSHNVFCSP 32

 Score = 318 (117.0 bits), Expect = 1.4e-34, Sum P(2) = 1.4e-34
 Identities = 69/147 (46%), Positives = 97/147 (65%), Frame = +3

Query:   141 PMSISSALAMVFMGAKGNTAAQMSQALCFSKIGGEDGDIHRGFQSLLVAINRTDTEYVLR 320
             P+SISSALAMV +GAKGNTA QM+QAL     +  E+ DIHR FQSLL  +N+  T+Y+LR
Sbjct:    32 PVSISSALAMVLLGAKGNTATQMAQALG---SLNTEE-DIHRAFQSLLTEVNKAGTQYLLR 87

Query:   321 TANGLFGEKSYDFLTGFTDSCGKFYQATIKQLDFVNDTEKSTTRVNSWVADKT--KAWKI 494
             TAN LFGEK+  FL+ F +SC +FY A +K+L F+    E+S   +N+WV+ KT  K  ++
Sbjct:    88 TANRLFGEKTCQFLSTFKESCLQFYHAELKELSFIRAAEESRKHINTWVSKKTEGKIEEL 147

Query:   495 IQTSLSHLEEPGIASSSCYCKACLSQP 575
             +  S    E   +  ++ Y K   ++P
Sbjct:   148 LPGSSIDAETRLVLVNAIYFKGKWNEP 174
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